

This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS ROME 000930

SIPDIS

HHS FOR FDA VEEK, CARNEVALE, CARSON, BREWER
USDA FOR DRITCHIE/FAS/EKUS

E.O. 12958: N/A

TAGS: [EAGR](#) [ETRD](#) [TBIO](#) [KPAO](#) [IT](#) [EUN](#)

SUBJECT: ITALY - OUTREACH ON NEW BIOTERRORISM REGULATIONS
AND AGRICULTURE TRADE

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PAGE 02 ROME 00930 061629Z

REF: A. STATE 36401

[B](#). ROME 812

[1](#)1. USING THE TALKING POINTS PROVIDED IN REF A, ON FEBRUARY 25 ECONOFF RAISED THE PROPOSED FDA REGULATIONS TO IMPLEMENT THE BIOTERRORISM ACT WITH SANDRO FANELLA, WTO OFFICE DIRECTOR AT THE FOREIGN TRADE OFFICE, MINISTRY OF PRODUCTIVE ACTIVITIES. WHILE APPRECIATING THE MOTIVATION BEHIND THE U.S. LEGISLATION, FANELLA NOTED THAT THE GOI HAD CONCERNS REGARDING THE POTENTIAL OBSTACLES TO TRADE THAT THE PROPOSED REGULATIONS COULD ENGENDER. HE RAISED THE FINANCIAL DIFFICULTY THAT SMALL-SCALE EXPORTERS MIGHT FACE IN ADHERING TO THE PROPOSED RULES, SPECIFICALLY THE REQUIREMENT REGARDING PRIOR NOTICE. ECONOFF NOTED THAT OUR PROPOSAL ATTEMPTS TO SIMPLIFY THE PROCESS BY ALLOWING BOTH REGISTRATION AND PRIOR NOTICE TO BE PERFORMED VIA THE INTERNET. WE ALSO EMPHASIZED THAT THE RULES ARE STILL JUST PROPOSALS, AND THAT THE U.S. WELCOMED COMMENTS FROM ANY INTERESTED PARTIES DURING THE PUBLIC COMMENT PERIOD. FANELLA FURTHER COMMENTED THAT, TO HIS KNOWLEDGE, THE EUROPEAN COMMISSION HAD NOT YET DISCUSSED THIS ISSUE WITH THE U.S., THOUGH HE HOPED SUCH TALKS WOULD BE FORTHCOMING.

[1](#)2. AS REPORTED REF B, EMBASSY HAS DELIVERED INFORMATION PACKETS ON THE PROPOSED REGULATIONS TO A VARIETY OF GOVERNMENT, INDUSTRY, AGRICULTURAL AND COMMERCIAL REPRESENTATIVES. WE HAVE ALSO CREATED A LINK ON THE EMBASSY'S WEBPAGE TO THE FDA WEB ADDRESS PROVIDED IN REF A. SEMBLER

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PAGE 03 ROME 00930 061629Z

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